

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW HAMPSHIRE

In re: Colgate-Palmolive
Softsoap Antibacterial Hand
Soap Marketing and Sales
Practices Litigation

Case No. 12-md-2320-PB
All Cases
Opinion No. 2013 DNH 038

MEMORANDUM AND ORDER

Consumers of Softsoap Antibacterial branded soap ("Softsoap Antibacterial") have filed a consolidated class action complaint against Colgate-Palmolive Company ("Colgate"), the manufacturer of Softsoap Antibacterial. Plaintiffs' claims, which are based entirely on state law, charge that Colgate is liable for damages because it induced class members to purchase Softsoap Antibacterial by making false and misleading marketing claims. Colgate has responded by arguing, among other things, that the action should be dismissed or stayed because the Food and Drug Administration ("FDA") has primary jurisdiction over certain factual questions that must be answered to resolve plaintiffs' claims. For the reasons set forth below, I reject Colgate's argument and deny its motion to dismiss or stay to the extent that it is based on the primary jurisdiction doctrine.

I. THE AMENDED COMPLAINT

The active ingredient in Softsoap Antibacterial is triclosan, a chemical that can function as an antibacterial and antifungal agent. The FDA has been studying the safety and effectiveness of triclosan in consumer hand soaps since the 1970s. In 1994, the agency announced that it lacked sufficient evidence to determine whether triclosan is safe and effective for use in consumer hand soaps, and it has not updated its assessment since then, though its review is ongoing.

Plaintiffs assert that numerous scientific studies over the last fifteen years have raised doubts about the safety and effectiveness of triclosan. For example, they claim that studies show that repeated use of triclosan hand soap can produce bacteria that are resistant to the chemical. Additionally, they assert that triclosan kills only some types of bacteria, and is classified as a chlorophenol, a class of chemicals that is suspected of causing cancer in humans. Further, they assert that numerous studies suggest that triclosan hand soaps are no more effective at killing bacteria than regular soap and water.

In light of the data questioning triclosan's safety and effectiveness, plaintiffs argue that Colgate's marketing strategy misled consumers. In particular, Plaintiffs claim that:

- Colgate's use of the "Softsoap Antibacterial" brand is false or misleading because it implies that antibacterial soaps with triclosan are more effective than non-triclosan liquid hand soaps or regular soap and water;
- Assertions that Softsoap Antibacterial "kills 99% of common germs" and "eliminates 99% of germs" are false or misleading because it does not actually kill 99% of germs;
- The assertion that Softsoap Antibacterial is "dermatologist tested" is false or misleading because it was not dermatologist tested;
- The assertion that Softsoap Antibacterial is "clinically proven to eliminate 99% of germs your family encounters" is false or misleading because Colgate has no clinical proof of its assertion;
- The assertion that the product "offers antibacterial protection" is false or misleading because Colgate either lacks facts to substantiate its claim or the claim is false;
- The statements "Goodbye germs. Hello world." are false or misleading because they incorrectly imply that Softsoap Antibacterial products are superior to regular soap and water and non-triclosan hand soaps; and
- The assertion that Softsoap Antibacterial is "America's most trusted hand soap" is false or misleading because Colgate lacks substantiation for its claim.

These allegations provide the basis for plaintiffs' consumer protection, breach of warranty, and unjust enrichment claims.¹ Plaintiffs seek monetary damages, restitution, and disgorgement of revenues. Plaintiffs originally sought injunctive relief as well, but in light of Colgate's disclosure that the company has ceased manufacturing and distributing consumer products containing triclosan, plaintiffs voluntarily abandoned their requests for injunctive relief.

I. STANDARD OF REVIEW

The defendant bases its motion to dismiss or stay on [Fed. R. Civ. P. 12\(b\)\(6\)](#). In considering a Rule 12(b)(6) motion, the court's review is generally limited to the matters asserted in the complaint. See [Curran v. Cousins](#), 509 F.3d 36, 44 (1st Cir. 2007). I must "accept as true the well-pleaded factual allegations of the complaint, draw all reasonable inferences

¹ The plaintiffs allege violations of the consumer protection statutes of five states: California, Florida, Illinois, Nevada, and New Jersey. They also bring common law claims for breach of express warranty (California, Florida, Illinois, Nevada, New Jersey, and South Carolina), breach of implied warranty (California, Florida, Nevada, New Jersey, and South Carolina), and unjust enrichment (Florida, Illinois, Nevada, New Jersey, and South Carolina).

therefrom in the plaintiff's favor and determine whether the complaint, so read, sets forth facts sufficient to justify recovery on any cognizable theory." [Martin v. Applied Cellular Tech.](#), 284 F.3d 1, 6 (1st Cir. 2002). The plaintiff must make factual allegations sufficient to "state a claim to relief that is plausible on its face." [Bell Atl. Corp. v. Twombly](#), 550 U.S. 544, 570 (2007). A claim is facially plausible when it pleads "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged. The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." [Ashcroft v. Iqbal](#), 556 U.S. 662, 678 (2009) (citations omitted).

To decide a Rule 12(b)(6) motion based on the primary jurisdiction doctrine, the court must determine whether referral to a federal agency is appropriate in light of [Iqbal](#) and [Twombly](#). [Iqbal](#), 556 U.S. at 678 (2009); [Twombly](#), 550 U.S. at 556. See [Cnty. of Santa Clara v. Astra USA, Inc.](#), 588 F.3d 1237, 1252 (9th Cir. 2009), *rev'd on other grounds* 131 S.Ct. 1342 (2011). Accordingly, it must decide "whether the complaint plausibly asserts a claim that would not implicate the

doctrine.” [Astra](#), 588 F.3d at 1252 (emphasis in original). If it does, then the court must deny the motion to dismiss with respect to that claim. [Davel Commc’n, Inc. v. Qwest Corp.](#), 460 F.3d 1075, 1088 (9th Cir. 2006) (citing [Iqbal](#), 565 U.S. at 678).

II. ANALYSIS

A. Legal Background: Primary Jurisdiction Doctrine

The primary jurisdiction doctrine applies when a claim that is originally cognizable in either the courts or an administrative agency “requires the resolution of issues which, under a regulatory scheme, have been placed within the special competence of an administrative body.” [United States v. W. Pac. R.R. Co.](#), 352 U.S. 59, 64 (1956). See [Tex. & Pac. Ry. Co. v. Abilene Cotton Oil Co.](#), 204 U.S. 426, 440-42 (1907) (referring an issue to the Interstate Commerce Commission in a case involving interpretation of a statute that, on its face, gave the courts and the ICC concurrent jurisdiction). Thus, despite its name, the primary jurisdiction doctrine is unrelated to a court’s subject matter jurisdiction, or power, to hear a dispute. [Mashpee Tribe v. New Seabury Corp.](#), 592 F.2d 575, 580 n.1 (1st Cir. 1979). It is, instead, “a prudential doctrine,”

Assoc. of Intern. Auto. Mfrs., Inc. v. Comm’r, Mass. Dept. of Evtl. Prot., 196 F.3d 302, 304 (1st Cir. 1999), that is primarily “concerned with promoting proper relationships between the courts and administrative agencies charged with particular regulatory duties.” W. Pac., 352 U.S. at 63.

The doctrine serves two primary purposes. First, it helps promote “national uniformity in the interpretation and application of a federal regulatory regime . . . by permitting the agency that has primary jurisdiction over the matter in question to have a first look at the problem.” Am. Auto. Mfrs. Ass’n v. Mass. Dep’t of Evtl. Prot., 163 F.3d 74, 81 (1st Cir. 1998). See also Tex. & Pac. Ry., 204 U.S. at 440-42 (emphasizing agencies’ ability to obtain uniformity in the interpretation of federal regulations). A second justification for the doctrine is that it promotes efficiency by allowing courts to capitalize on the expertise that agencies often develop in deciding technical factual questions. Am. Auto. 163 F.3d at 81. See also Far E. Conference v. United States, 342 U.S. 570, 574-75 (emphasizing agencies’ “specialized competence”

to determine facts “underlying legal issues”).²

When a court encounters a factual issue that is within an agency’s special competence, it may suspend the judicial process “pending referral of such issues to the administrative body for its views.”³ [Israel v. Baxter Lab., Inc.](#), 466 F.2d 272, 281 (D.C. Cir. 1972). There is, however, “[n]o fixed formula” for determining when a court should refer a case. [W. Pac.](#), 352 U.S.

² There are additional justifications for the doctrine, including that “[d]eference can dam [a] potential flood of suits seeking de novo review of agency determination.” [Mashpee Tribe](#), 592 F.2d at 581. Deference may also “permit an agency to follow through and supervise earlier actions,” and the “doctrine recognizes that some problems are better solved by the more flexible procedures possible before agencies not bound by Article III limitations.” [Id.](#) Additionally, “agencies often have prescribed procedures specially designed to resolve particular kinds of disputes.” [Id.](#)

³ Courts use the term “referral” loosely because, normally, there will be no mechanism by which a court can demand that an agency decide a certain issue. [Reiter v. Cooper](#), 507 U.S. 258, 267 n.3 (1993). If there is such a mechanism, “that mechanism should be used.” [Am. Auto.](#), 163 F.3d at 82. [E.g.](#), [Dartmouth-Hitchcock Clinic v. Toumpas](#), No. 11-CV-358-SM, 2012 WL 4482857, *5 (D.N.H. Sept. 27, 2012). Typically, however, a court will stay the proceedings so the plaintiff has a reasonable amount of time to request a ruling from the agency. [Dartmouth-Hitchcock](#), 2012 WL 4482857, at *5; [Davel](#), 460 F.3d at 1087 (“[T]he parties are responsible for initiating the appropriate proceedings before the agency.”). The court may also decline to refer the case, [Am. Auto.](#), 163 F.3d. at 81, or dismiss it without prejudice. [Israel v. Baxter Lab., Inc.](#), 466 F.2d 272, 281 (1st Cir. 1972).

at 64. Accordingly, courts have developed various criteria to guide their discretion. See, e.g., Ellis v. Tribune Television Co., 443 F.3d 71, 81-83 (2d Cir. 2006); Syntek Semiconductor Co., Ltd. v. Microchip Tech., Inc., 307 F.3d 775, 781 (9th Cir. 2002); Mashpee Tribe, 592 F.2d at 580-81.

The First Circuit considers three related factors in determining whether to apply the doctrine: (1) whether an important issue in the case lies “at the heart of an administrative agency’s task,”⁴ Ricci v. Chi. Mercantile Exch.,

⁴ The first First Circuit factor has generally been phrased as follows: “whether the agency determination lay at the heart of the task assigned the agency by Congress.” See, e.g., Pejepscot Indus. Park, Inc. v. Maine Central R. Co., 215 F.3d 195, 205 (1st Cir. 2000); Am. Auto., 163 F.3d at 81; Mashpee Tribe, 592 F.2d at 580-81. The First Circuit first described this factor in Mashpee Tribe, deriving it from language in two Supreme Court cases. See Mashpee Tribe, 592 F.2d at 580-81 (citing Ricci v. Chi. Mercantile Exch., 409 U.S. 289, 305 (1973); Chi. Mercantile Exch. v. Deaktor, 414 U.S. 113, 114 (1973)). Because the factor as articulated in the Supreme Court cases more clearly expresses the idea that referral is appropriate when a factual issue arising in the litigation lies at the heart of an agency’s regulatory authority, and because the First Circuit nowhere suggests that the change in language implies any shift in meaning, I use the Supreme Court’s language instead of the First Circuit’s. See Ricci, 409 U.S. at 305 (concluding that “questions about the scope, meaning, and significance of membership rules” under the Commodity Exchange Act were “matters typically lying at the heart of an administrative agency’s task” and referring the case to the Commission); Deaktor, 414 U.S. at 114 (concluding that “administrative adjudication of alleged

409 U.S. 289, 305 (1973) (cited in Mashpee Tribe, 592 F.2d at 580-81); (2) whether the issue requires the agency's technical expertise, Mashpee Tribe, 592 F.2d at 580-81; and (3) whether, "though perhaps not determinative, the agency determination would materially aid the court."⁵ Id. at 581. These factors animate the purposes of the primary jurisdiction doctrine. See Am. Auto., 163 F.3d at 81 ("In every case, the question is whether the reasons for the existence of the doctrine are present and whether the purposes it serves will be aided by its application in the particular litigation.") (quoting W. Pac., 352 U.S. at 81).

The first factor reflects the doctrine's goals of avoiding disruption of an agency's regulatory regime and promoting

violations of the C[ommodities and] E[xchange] A[ct] lay at the heart of the task assigned the Commission by Congress," and referring the case to the Commission).

⁵ I apply the First Circuit factors because, in multidistrict litigation, the transferee court ordinarily applies the substantive and procedural federal law of the circuit in which it sits. In re Korean Air Lines Disaster of Sept. 1, 1983, 829 F.2d 1171, 1176 (D.C. Cir. 1987) (substantive law); In re Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine) Prod. Liab. Litig., 294 F. Supp. 2d 667, 672 (E.D. Pa. 2003) (procedural law) (citing Korean Air Lines, 829 F. 2d at 1174). Additionally, the parties presented their arguments in terms of the First Circuit factors.

uniformity in regulatory interpretation. See id. It manifests the courts' respect for executive agencies' power to perform their core functions as assigned by Congress. The second two factors reflect the doctrine's goal of promoting judicial economy through an efficient allocation of courts' and agencies' overlapping duties. See Mashpee Tribe, 592 F.2d at 580 n.1. These factors ask, essentially, whether and how the court might benefit from an agency's fact-finding abilities. See United States v. Philip Morris USA Inc., 686 F.3d 832, 837 (D.C. Cir. 2012) (noting that the "doctrine is rooted in part in judicial efficiency" and should be applied where invoking it "could enhance court decision-making and efficiency by allowing the court to take advantage of [that] administrative expertise") (quoting Chabner v. United of Omaha Life Ins. Co., 225 F.3d 1042, 1051 (9th Cir. 2000)).

These three factors "must be balanced against the potential for delay inherent in the decision to refer an issue to an administrative agency." Am. Auto., 163 F.3d at 81. In the discussion that follows, I explain how each of these factors applies in the present case.

B. Applying the Primary Jurisdiction Doctrine

1. Whether an important issue in the case lies at the heart of the agency's regulatory authority

The first factor is whether an issue in the case lies "at the heart of an administrative agency's task." [Ricci](#), 409 U.S. at 305 (cited in [Mashpee Tribe](#), 592 F.2d at 580-81). If a central, factual question in a case is specifically within an agency's delegated authority to decide, courts often refer the case to the relevant agency to promote uniformity, avoid disrupting a regulatory regime, and demonstrate respect for the agency's ability to perform its core functions. See, e.g., Commonwealth of Mass. v. Blackstone Valley, 67 F.3d 981, 992 (referring case to the EPA because the question at the heart of the case - whether a particular substance is "hazardous" within the meaning of federal regulations - was "specifically within the scope of the EPA's delegated authority"); [Palmer Foundry, Inc. v. Delta-HA, Inc.](#), 319 F. Supp. 2d 110, 114 (D. Mass. 2004) (referring the case to OSHA because whether resin is an "oxidizer" - the central question before the court - was "at the heart of the agency's assignment from Congress"). In contrast, questions as to whether the consumer "received what [he]

bargained for,” which arise frequently in consumer protection suits, ordinarily do not lie at the heart of agencies’ Congressional mandates. [Torres-Hernandez v. CVT Prepaid Solutions, Inc.](#), 3:08-CV-1057-FLW, 2008 WL 5381227, at *4 (D.N.J. Dec. 17, 2008) (refusing to apply the doctrine where the issue was whether the defendant defrauded consumers of pre-paid calling cards through false advertising).

To determine whether an issue in this case lies at the heart of the FDA’s regulatory authority, I first describe the FDA’s power in this area and the agency’s regulatory efforts with respect to over-the-counter consumer soaps containing triclosan. I then turn to an analysis of the specific factual issues that are likely to arise in this case.

a. The FDA’s Regulatory Authority

The FDA’s mandate includes the responsibility to ensure the safety, effectiveness, and proper labeling of over-the-counter (“OTC”) drugs. 21 U.S.C. § 393(b)(1), 2(B). In 1972, the agency categorized all OTC drugs into therapeutic classes.⁶ It

⁶ There are currently over 80 therapeutic classes of drugs (i.e. antacids, cold remedies, antimicrobial products, etc.). Drugs, Drug Applications for Over-the-Counter (OTC) Drugs, <http://www.fda.gov/drugs/developmentapprovalprocess/howdrugsared>

identified "OTC Topical Antimicrobial Products," including consumer antibacterial products containing triclosan, as one such class. [Over-the-Counter Antibacterial Ingredients in Drug Products for Repeated Daily Human Use](#), 37 Fed. Reg. 235 (Jan. 7, 1972). The FDA also established procedures for developing monographs to identify the conditions under which the drugs in each class would be considered safe, effective, and not misbranded.⁷ [Procedures for Classification of Over-the-Counter Drugs](#), 37 Fed. Reg. 85 (Jan. 5, 1972) (codified at 21 C.F.R. § 330.10). Each monograph identifies acceptable ingredients for drug products in the class, and specifies proper doses,

[developedandapproved/approvalapplications/over-the-counterdrugs/default.htm](#).

⁷ OTC drugs already on the market when the monograph process was announced in 1972 were permitted to remain on the market pending agency review. [Over-the-Counter Drugs](#), 37 Fed. Reg. 85, 86 (Jan. 5, 1972); cf. [Thompson Med. Co., Inc. v. FTC](#), 791 F.2d 189, 192 (D.C. Cir 1986) (involving false advertising claims relating to an analgesic, the safety and effectiveness of which the FDA had been studying since 1962). The FDA has not completed its review of the safety and effectiveness of triclosan hand soaps. Therefore, triclosan hand soaps are permitted to remain on the market. See [Over-the-Counter Drugs](#), 37 Fed. Reg. 85, 86 (Jan. 5, 1972).

formulations, and labeling requirements.⁸

The monograph process occurs in multiple stages over multiple years. 21 C.F.R. § 330.1. Drugs must conform to monograph conditions, and no aspect of the product's label may be false or misleading. 21 U.S.C. § 352(a). Labeling is defined as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. § 321(m).

b. The FDA's Regulation of Consumer Hand Soaps Containing Triclosan

The FDA began its efforts to regulate consumer hand soaps containing triclosan in the 1970s, issuing a proposed monograph on topical antimicrobial products - covering consumer hand soaps, antimicrobial products used by health care professionals, and those used by food handlers - in 1974. Proposal to Establish a Monograph for OTC Topical Antimicrobial Products, 39 Fed. Reg. 33103 (Sept. 13, 1974). It categorized triclosan as a Category III ingredient when used in consumer hand soaps,

⁸ The FDA also promulgates general labeling requirements that apply to all OTC drugs, see 21 C.F.R. § 201.66; 21 C.F.R. § 330.1, and prescribes specific labeling requirements for major classes of drugs. See 21 C.F.R. § 330-355.

meaning there was insufficient data to determine whether the ingredient is safe and effective for daily, at-home hand washing. Id. at 33115.

In 1978, the FDA issued its first tentative final monograph ("TFM") covering triclosan products. [Over-the-Counter Drugs Generally Recognized as Safe, Effective and not Misbranded](#), 43 Fed. Reg. 1210 (Jan. 6, 1978). In 1991, the agency reopened the administrative record to collect additional information and issued an amended TFM. [Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Tentative Final Monograph for First Aid Antiseptic Drug Products](#), 56 Fed. Reg. 33644-01 (July 22, 1991). At that time, triclosan "remained classified in Category III for safety for long-term use" and was tentatively classified in Category III for effectiveness. Id. at 33665. The TFM proposed prohibiting Category III ingredients - including triclosan when used in consumer hand soaps - beginning one year after the final monograph's publication. Id. at 33645.

In 2003, the agency reopened the record yet again to accept additional data on antimicrobial drug products. [Over-the-Counter Drug Products; Safety and Efficacy Review](#), 68 Fed. Reg. 75585-01 (Dec. 31, 2003). Two years later, a representative of

the Department of Health and Human Services noted in a letter to Congress that the "FDA was not aware of any evidence that antibacterial washes were superior to plain soap and water for reducing transmission of or preventing infection for consumers." Letter to Senator Edward J. Markey from Jeanne Ireland, Department of Health and Human Services Commissioner for Legislation, Feb. 23, 2010, Doc. No. 26-5 at 7 ("Ireland Letter").

In 2009, the FDA announced that it would reissue the 1994 TFM in multiple segments addressing topical antimicrobial drug products intended for use by consumers, health care professionals, and food handlers separately. Ireland Letter at 1 n.1. It explained that triclosan hand soaps will be analyzed under a monograph specifically governing consumer antiseptics. Id. The agency has been unable to provide "a detailed timeline for completion of this process," but claims to be "working diligently to publish the proposed rule." Ireland Letter at 2. See also Declaration of Charles J. Ganley, M.D., Director of the Office of Drug Evaluation and Research, FDA, Dec. 10, 2010, Doc. No. 26-6 at 35.

In the forthcoming TFM, the FDA will detail its concerns about the potential for long-term negative impacts of triclosan exposure and seek additional data and information. Ireland Letter at 2. The FDA will use that information to prepare a final monograph. Id. The final monograph will establish parameters for using triclosan in consumer hand soaps. It could ban the use of triclosan, or limit its use except in certain concentrations. The monograph will also establish requirements for the proper labeling of consumer hand soaps. The final monograph will be subject to challenge in federal court. See 212 C.F.R. § 330.10(a)(11).

c. The Factual Issues in This Case

In this case, plaintiffs seek to prove that Colgate made implied claims that Softsoap Antibacterial is superior to other products; that it misrepresented Softsoap Antibacterial's effectiveness; and that it misled consumers with unsubstantiated claims about its products. To resolve those claims, the court will examine the state of scientific knowledge in the past, when Colgate made its advertising and labeling claims relating to Softsoap Antibacterial's safety and effectiveness. It will determine what data Colgate possessed to support its marketing

claims at the time they were made and whether Colgate ignored data that contradicted its claims. The court will also determine how a reasonable consumer would have interpreted Colgate's marketing campaign for Softsoap Antibacterial. Essentially, this litigation is backward-looking; it seeks to determine whether past conduct was misleading.

The FDA's monograph process, in contrast, is forward-looking. It will determine the permissible content of future product labels. It will establish the permissible concentrations of triclosan in consumer hand soaps, if it permits use of the ingredient at all. The monograph will articulate the FDA's findings, based on the current state of scientific knowledge, about the safety and effectiveness of triclosan as used in consumer hand soaps.

The FDA will not draw any factual conclusions about Colgate's past conduct. The agency will not address whether Colgate's past advertising claims were substantiated. Nor will the FDA's monograph shed light on what information Colgate knew or could have known at the time it made the advertising and labeling claims at issue in this case. The FDA will not address whether Colgate's past product labels or advertising claims were

misleading when they were made or make any pronouncement on how a reasonable consumer would interpret Colgate's marketing claims. Accordingly, although the FDA's conclusions may touch on some issues in this case, the case does not turn on factual disputes that lie at the heart of the FDA's regulatory authority. The first factor thus weighs against applying the doctrine.

2. The need for agency expertise

Next, I consider whether agency expertise is necessary to decide a technical factual question in the case. See [Mashpee Tribe](#), 592 F.2d at 580. Efficiency and the proper allocation of agencies' and courts' duties may support referral of a factual question to a federal agency. See [Am. Auto.](#), 163 F.3d at 83 (referring the case to the EPA because a central fact question in the case would "clearly benefit from [the agency's] deep familiarity with the C[lean] A[ir] A[ct] and the public policy considerations that underlie these statutory provisions"). Here, however, the central issues that will have to be answered to resolve plaintiffs' damage claims do not require the expertise of the FDA.

First, plaintiffs' claims that Colgate's advertising statements were unsubstantiated will require a factfinder to measure the statements that Colgate made about Softsoap Antibacterial against the scientific evidence that was available to Colgate when it made its claims. This type of historical fact finding is well within the competence of a court to conduct. Cf. [Tripledge Prod., Inc. v. Whitney Res., Ltd.](#), 735 F. Supp. 1154, 1165 (E.D.N.Y. 1990).

Second, plaintiffs' claims that Colgate made false and misleading statements about Softsoap Antibacterial will depend to a significant extent on how consumers interpreted Colgate's statements. The FDA does not have technical expertise related to questions of fraud and deceit. Courts, by contrast, routinely determine whether past conduct or statements were false or misleading. For example, in [Dana Corp.](#), the Sixth Circuit rejected the primary jurisdiction doctrine, concluding that the state agency overseeing insurance contracts had no special expertise relating to allegations of fraudulent misrepresentations in administrative services only contracts. 900 F.2d at 889. Similarly, a district court rejected referral to the Federal Communications Commission in [Torres-Hernandez](#), a

case that required a determination of whether the defendant defrauded consumers of pre-paid calling cards by failing to provide the advertised number of minutes on each card. 2008 WL 5381227, at *1. The court concluded that claims brought under the New Jersey Consumer Fraud Act were properly before the court. Id. at *4. In Ackerman, the court concluded that questions about “whether consumers could reasonably be misled by [] violations” of FDA labeling regulations governing nutrient-content claims was a question the court was competent to decide. 2010 WL 2925955, at *14. See also Chacanaca, 752 F. Supp. 2d at 1122 (rejecting the primary jurisdiction doctrine because plaintiffs “assert that defendant has violated FDA regulations and marketed a product that could mislead a reasonable consumer,” a question within the court’s ken).

Third, where (as here) marketing claims relate to the comparative safety or efficacy of a drug, the Federal Trade Commission (“FTC”), and not the FDA, generally has enforcement authority. Bristol-Myers Co. v. Fed. Trade Comm’n, 738 F.2d 554, 559 (2d Cir. 1984) (“[T]he FDA is concerned only with evaluating absolute safety and efficacy, and not with the questions of comparative safety and efficacy that arise in OTC

drug advertising.”); [Thompson](#), 791 F.2d at 192 (stating that the FDA “has no warrant” to address the defendant’s claim that Aspercreme is more effective than aspirin because “the FDA’s evaluation of OTC drugs only involves a determination of the safety and efficacy of individual drugs”). Since both federal courts and the FTC are competent to decide whether labeling and advertising statements were false or misleading, the FDA’s special expertise is not required to resolve these issues. Thus, the second factor also weighs against applying the primary jurisdiction doctrine.

3. Whether an agency decision would materially aid the court in resolving the case

Colgate has also failed to show how a decision by the FDA would “materially aid the court” in resolving the plaintiffs’ claims. [Mashpee Tribe](#), 592 F.2d at 581. When an agency determination of some factual issue would “be of great help to” a court in deciding a legal issue, referral is often appropriate. [Ricci](#), 409 U.S. at 307 (referring the case to the Commodity Exchange Commission because the agency’s determination of a factual question would enable the court to make “a more informed and precise determination . . . of the scope and

meaning of the statute").

Originally, Colgate claimed that the factual determinations it expects the FDA to make in its forthcoming monograph will be essential to resolving this case. Doc. No. 26-1 at 14-16. Colgate, however retreated from this assertion during the hearing on its motion and agreed that, at most, the monograph may provide "some data that might be useful to one side or the other." Tr. 29. Colgate has not demonstrated that the forthcoming monograph would materially aid or "be of great help to" this court in resolving the issues in the case. Ricci, 409 U.S. at 307; Mashpee Tribe, 592 F.2d at 581.

4. The prospects of a timely resolution of the case if the issue is referred

Any minimal value that an FDA ruling might have on the resolution of this case is greatly outweighed by the harm that the plaintiffs will suffer if the action is delayed, potentially for several years, until the FDA makes a determination concerning the effectiveness of hand soaps containing triclosan. As I have noted, the FDA began investigating triclosan products in 1972. Since then, it has issued two TFMs and reopened the administrative record on multiple occasions. Several years ago,

the agency decided to split its original monograph on triclosan products into three separate monographs. Since then, the agency has missed multiple self-imposed deadlines for publishing the TFM, most recently in February 2013. See Regulatory Agenda, Department of Health and Human Services, Jan. 9. 2013, Doc. No. 42-1.

Once a TFM is issued, the agency will require a minimum of fourteen more months to prepare the final monograph in accordance with the procedures set out in the regulations. See 21 C.F.R. § 330.10. Thus, even if the TFM were issued tomorrow, the final monograph would not enter into force until May 2014 at the earliest. Moreover, the final monograph is not the end of the road: It may be appealed to the federal courts, and the Commissioner has discretion to stay the effective date for all or part of the monograph pending final court adjudication. Id. This long unavoidable delay in issuing a final monograph on consumer antiseptics weighs strongly in favor of rejecting the doctrine. See Ackerman, 2010 WL 2925955, at *14 (declining to apply the primary jurisdiction doctrine in part because “deferral to the FDA is unlikely to result in a timely resolution of plaintiff’s claims”).

III. CONCLUSION

As I have explained, it is unlikely that any determination by the FDA concerning the future marketing and sale of triclosan hand soap will have any substantial effect on plaintiffs' retrospective claims for damages. Nor is this court likely to benefit materially from the FDA's technical expertise. Given the limited benefit to be derived by waiting, and the substantial harm that plaintiffs will suffer if the action is delayed to await FDA action, I determine that this is not an appropriate case in which to apply the primary jurisdiction doctrine. Accordingly, I deny Colgate's motion to dismiss (Doc. No. 26) to the extent that it rests on primary jurisdiction grounds.

SO ORDERED.

/s/Paul Barbadoro
Paul Barbadoro
United States District Judge

March 18, 2013

cc: Counsel of Record